SUPPORTING STATEMENT

INFANT FORMULA RECALL REGULATIONS
(21 CFR Part 107, Subpart E)

OMB Control No. 0910-0188

A. JUSTIFICATION

1. Circumstances that Make Collection of Information Necessary

The Infant Formula Act of 1980 amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 412 (21 U.S.C. 350a) which provides for more stringent regulatory control over infant formula manufacturing and processing. Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall (Attachment A). The Food and Drug Administration's (FDA) infant formula recall regulations (part 107, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions (Attachment B).

In 1986, Congress amended the Infant Formula Act of 1980 to address concerns expressed by industry, the agency and consumers regarding the effectiveness and rapidity of the infant formula recall procedures. The agency has amended its recall regulations to reflect the statutory changes effected by the Infant Formula Act. The Final Rule was published January 27, 1989 (Attachment C).

We are requesting approval from OMB on the following collections of information requirements:

21 CFR 107.230 - Reporting

Requires each recalling firm to evaluate the hazard to human health, devise a written recall strategy, promptly notify each affected direct account (customer) about the recall, and furnish the appropriate FDA district office with copies of these documents.

If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice.

21 CFR 107.240 - Reporting

Requires the recalling firm to notify the appropriate FDA district office of the recall by telephone within 24 hours, to submit a written report to that office within 14 days, and to submit a written status report at least every 14 days until the recall is terminated.

21 CFR 107.250 - Reporting

Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence.

21 CFR 107.260 - Disclosure - Notification

Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications

21 CFR 107.280 - Recordkeeping

Requires the recalling firm to maintain distribution records, for at least 1 year after the expiration of the shelf life of the infant formula, to facilitate location of the product being recalled. **(Language Approval Only - See item 12b. for explanation.)**

2. How, by Whom, and for What Purpose the Information is Used

Manufacturers must establish certain recordkeeping requirements, reporting procedures and operating protocols necessary to perform an effective recall of products that are in violation of the laws and regulations administered by FDA.

The manufacturers keep records of product shipments and consignees. In the event of a recall, a manufacturer must collate this information and notify direct distributors and other buyers by the established process so that the orderly return of the recalled product to the manufacturer takes place. In some cases, depending on the severity of any health related hazard of the product under recall, the manufacturer must make additional announcements to the consuming public so that any customer having already purchased a hazardous product will be alerted as to the potential problem and encouraged to return the product.

The information collected by the manufacturer is provided to FDA to enable FDA to conduct recall checks at various points in the product's distribution chain to determine the effectiveness of the recall. Obviously, the consequence of not having this information collection would be that products identified as adulterated or misbranded would not be quickly and efficiently pulled off the market.

3. Use of Improved Information Technology

FDA has emphasized to manufacturers the importance of coding each lot of formula produced and retaining the shipping and distribution records for each lot. The coding identifies the location and date of manufacture, and what line within the plant that produced the problem product. When it becomes necessary to recall a product, this information allows the manufacturer to locate the exact point in the manufacturing process or the distribution chain where the problem occurred. This automated system handles the recordkeeping routinely, allows for the orderly return of the problem product to the manufacturer, and results in significant savings in time and money in the event a recall is necessary.

4. Identification of Duplication and Similar Information Already Available

FDA is the only Federal agency that collects this information. No duplication can occur as each manufacturer is responsible for his own shipping routes and records. Each recall of an infant formula product is unique. The information needed to accomplish the recall is the exact shipping and distribution pattern for a specific lot or group of lots of a particular product. The information is not available from any other source.

5. Small Businesses

The production of processed foods requires that producers take on a very high degree of responsibility, especially for infant formula products. In the event of a recall, the safety of infants is involved and the first priority is the removal of hazardous foods (infant formulas) from channels of commerce. FDA will provide assistance to any firm in achieving this goal. Also, FDA aids small businesses in dealing with the requirements through the Office of Small Manufacturers Assistance and through the scientific and administrative staffs within the Agency.

6. Consequences if Data were Collected Less Frequently

A recall is the result of a realization that an adulterated or misbranded infant formula which presents a risk to human health is present in the marketplace. The frequency of such recalls cannot be predicted. If manufacturers were more reluctant to conduct recalls, FDA, in order to protect the public health, would be required to initiate seizure action or another type of regulatory action to remove these products from channels of commerce.

7. Special Circumstances

The reporting activity is more intense than that specified in 5 CFR 1320.5. Concern over the conduct of the infant formula recalls was the basis for Congressional action in amending the Act to require the reporting activity of §§ 107.240 and 107.250 (21 CFR 107.240 and 107.250). From a public health perspective, this level of activity is required because of the risk to the health of the infant consumer and because these products are used as the sole source of sustenance for this highly vulnerable population group.

For FDA to efficiently and effectively monitor the recall of all infant formulas and fulfill its recall oversight responsibilities under Section 412(d)(1)(A) of the act, the agency must be made aware at the earliest possible time that a recall is being conducted. Therefore, 21 CFR 107.240 requires that a firm promptly notify the agency by telephone at the time that the firm decides to initiate the recall. This early notification allows the agency the opportunity to evaluate and comment on the recalling firm's strategy. In addition, such notification eliminates needless regulatory actions which the agency might otherwise take against violative products in order to protect the public health. For example, FDA would not normally initiate a seizure action against a violative infant formula if it knew that the shipment was being recalled by the responsible firm.

In 1978, a major manufacturer of infant formulas reformulated two of his products by discontinuing the addition of salt. The reformulation resulted in products containing an inadequate amount of chloride, an essential nutrient. By mid-1979, hypochloremic metabolic alkalosis, a syndrome associated with chloride deficiency, had been diagnosed in a substantial number of infants. Most of the cases resulted from prolonged and exclusive use of the reformulated products. A recall was instituted for these defective products, however, the recall did not result in the prompt removal of all the chloride-deficient formulas from many retailers and wholesalers.

After reviewing the matter, Congress acted to improve the protection of infants using formula products by amending the act to establish in Section 412(f)(1) (21 U.S.C. 350a(f)) that if a recall is begun by a manufacturer, the manufacturer shall, "not later than the 14th day after the beginning of such recall and at least once every 14 days thereafter until the recall is terminated, report to the Secretary the actions taken to implement the recall." These sections of the act are the statutory bases of 21 CFR 107.250.

8. Consultation Outside the Agency

On February 23, 1999 (64 FR 8832), FDA published a 60-day notice in the Federal Register soliciting public comment as required under the PRA of 1995 (Attachment D). FDA did not receive any comments regarding the information collection requirements contained in this submission.

9. Payment or Gifts

No payment or gifts are offered to respondents for fulfilling their obligation to provide information.

10. Confidentiality

FDA provides no assurance of confidentiality to firms that voluntarily decide to, or are required to, conduct recalls.

11. Sensitive Questions

The information required to conduct a recall does not involve any question of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates

The total estimated annual burden for this collection of information is 18,956 hours.

a. Reporting.

The Agency records verify 3 recalls in the last 3 years or 1 recall annually.

b. Recordkeeping.

No burden has been estimated for the recordkeeping requirement in §107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

The burden hours estimated for this collection of information, per recall, is as follows:

Estimated Annual Reporting Burden					
21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	3	1	3	4,500	13,500
107.240	3	1	3	1,482	4,446
107.250	3	1	3	120	360
107.260	1	1	1	650	650
Total					18,956

Annualized Burden Hour Costs for Respondents.

Estimates of annualized costs to manufacturers of infant formula are based on the recalls that have occurred since the Infant Formula Act passed in 1980. Because no information is required to be supplied except in the event a recall is initiated, the cost to both government and infant formula manufacturer is zero in the event no recalls are conducted.

The estimated cost to the manufacturers per recall is based on an hourly wage (including benefits) of $40/hour for an estimated time of 18,956 hours or approximately $758,240. This estimate was made by Agency staff who work in the program area and are familiar with manufacturing procedures and practices.

13. Costs to Respondents

There are no capital costs or operating and maintenance costs associated with this collection.

14. Cost to the Federal Government

The cost per recall is estimated to be approximately $95,744. This is based on the salaries of five (5) FTE's at GS 13-4 ($63,829/year) who spend an estimated 0.3 man-years each or a total burden of 3,100 hours. (5 FTE x $63,829/yr x 0.3 m-yr/FTE = $95,744)

15. Change in Burden

The estimated burden in this new request for clearance is 18,956 hours for an increase of 15,580 hours. This increase is due to a clerical error in the previous submission for OMB

approval (12/8/96) in the number of respondents. That number should have been 3 instead of .5 This submission corrects that error.

16. Publication of Collected Information

Once a recall of infant formula has been determined to be necessary, the firm is required to notify each of its affected accounts of the recall, and instruct each consignee to report whether or not they are in possession of the recalled infant formula and include a means to do so. If necessary a public warning is to be given.

17. Approval for NOT Displaying Expiration Date

We are not seeking approval for NOT displaying the expiration date.

18. Exception to the Certification Statement; Item 19, OMB Form 83-I.

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no plans to publish the information collected under the provisions of this regulation for statistical use. The collection of information required under the provisions of this regulation does not employ statistical methods.